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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 10/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,073

Applicant(s)

FURST, JOSEPH G.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/11/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-23 and 35-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-23, 35-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3, 5-7, 11. 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 16 is objected to because of an apparent informality, which can be corrected as follows: "claim 1" should be replaced by —claim 15— in order to provide an antecedent basis for "said biological agent." For examination purposes, the examiner presumed that this correction was done.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification (pg. 16, lines 8-13) describes a balloon with "slots 260 to allow delivery of compound 210 into body passageway A," but does not disclose that a biological agent is delivered from "at least one opening...from an interior of said balloon." That is, it is not certain whether the slots are such openings or a feature of the exterior surface of the balloon.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 8-10, 13-15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fontaine (5,443,498). Fontaine discloses, in figures 5, 6, and 12-14, an expandable intraluminal graft (8) for use within a body cavity or blood vessel, where the graft has a body member having first and second ends (10a-c, 12a-c) with a plurality of smooth end regions, a wall surface formed by a plurality of intersecting elongated members (10, 12, 14), wires, or bars (see col. 5, lines 50-52); the substantially same first and second cross-sectional shapes, and the substantially same longitudinal length when the body member is in the first and second cross-sectional shapes (see claim 1 of Fontaine); where the body member is made of a material visible under fluroscopy (see col. 5, lines 40-46), where the first cross-sectional shape is substantially circular, and where body member has a biological agent at least partially coated on the surface (see col. 5, lines 46-49).

6. Claims 1-4, 6, 7, 12-15, 18, and 22-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Israel et al. (5,733,303). Israel et al. disclose, in figures 1-3, an

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expandable intraluminal graft (30) for use within a body cavity or blood vessel, where the graft has a body member having first and second ends with a plurality of smooth end regions (17), a wall surface formed by a plurality of intersecting elongated members (11, 12), wires, or bars (see col. 4, lines 26-33) forming segments having at least four intersecting elongated members; the substantially same first and second cross-sectional shapes, and the substantially same longitudinal length when the body member is in the first and second cross-sectional shapes (see col. 1, lines 52-54); where the body member is made of an etched, metal material visible under fluroscopy (see col. 4, lines 26-34), where the first cross-sectional shape is substantially circular, where body member has a biological agent at least partially coated on the surface (see col. 4, lines 33-36), where the graft has at least one, bendable, "U"-shaped connector (18) and two body members (see fig. 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 11, 16, 17, 19, 20, and 35-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israel et al. in view of Fearnot et al. (5,609,629). Israel et al. disclose an expandable intraluminal graft substantially as claimed, but do not disclose a body member at least partially treated with Gamma or Beta radiation or a biological agent for inhibiting or reducing restenosis, vascular narrowing, in-stent restenosis, and combinations thereof; a biological agent including a platelet inhibitor, a PDGF inhibitor, or trapidil; and a body member with a mounting substance that at least partially delays delivery of the biological agent into a body cavity. Fearnot et al. teach, in col. 8, line 20 to col. 10, line 16, a graft with a body member (12) at least partially treated with Gamma or Beta radiation or a biological agent for inhibiting or reducing restenosis, vascular narrowing, in-stent restenosis, and combinations thereof; a biological agent including a platelet inhibitor, a PDGF inhibitor, or trapidil; and a body member with a mounting substance (porous layer 20 and/or coating layer 16) that at least partially delays delivery of the biological agent into a body cavity. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Fearnot et al., to modify the graft of Israel et al. so that it has body members treated as claimed. Such a coated graft would allow the introduction of bioactive or therapeutic materials into a body cavity.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fischell et al. (5,059,166) teach a graft treated with radiation.

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Kanesaka et al. (5,776,183) teach an expandable graft. Rowe (6,146,358) teaches a balloon and graft for delivery of therapeutic agents.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached at (703) 308-2496.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9302.

A handwritten signature in black ink that reads "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

October 1, 2003